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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEWART COLE,
ROLAND BUCHRIESER-BROSCH, STEPHEN GORDON, and
ALAIN BILLAULT

Appeal 2009-013916
Application 10/802,796
Technology Center 1600

Before ERIC GRIMES, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to polypeptides. The Examiner rejected the claims as lacking utility and enablement.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 51-54 and 57 are pending and on appeal (App. Br. 1). Claim 51 is representative and reads as follows:

> 51. A purified polypeptide, encoded by a polynucleotide comprising an Open Reading Frame contained within SEQ ID NO: 1, wherein the polynucleotide is selected from:
> (a) nucleotide 1,696,019 through nucleotide 1,697,420 of the Mycobacterium tuberculosis chromosome;
> (b) nucleotide 1,696,019 through nucleotide 1,699,892 of the Mycobacterium tuberculosis chromosome;
> (c) nucleotide 1,696,019 through nucleotide 1,701,088 of the Mycobacterium tuberculosis chromosome;
> (d) nucleotide 1,696,019 through nucleotide 1,702,588 of the Mycobacterium tuberculosis chromosome;
> (e) nucleotide 1,696,019 through nucleotide 1,704,091 of the Mycobacterium tuberculosis chromosome;
> (f) nucleotide 1,696,019 through nucleotide 1,705,056 of the Mycobacterium tuberculosis chromosome;
> (g) nucleotide 1,696,019 through nucleotide 1,705,784 of the Mycobacterium tuberculosis chromosome;
> (h) nucleotide 1,696,019 through nucleotide 1,706,593 of the Mycobacterium tuberculosis chromosome;
> (i) nucleotide 1,696,019 through nucleotide 1,707,524 of the Mycobacterium tuberculosis chromosome; or
> (j) nucleotide 1,696,019 through nucleotide 1,708,648 of the Mycobacterium tuberculosis chromosome.

The following rejections are before us for review:

(1) Claims 51-54 and 57, rejected under 35 U.S.C. § 101 as being unsupported by a substantial asserted utility or a well established utility (Ans. 3); and

(2) Claims 51-54 and 57, under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (Ans. 3-4).

DISCUSSION

In finding that the claimed polypeptides lack utility, the Examiner reasons that the Specification "suggests but does not demonstrate that the claimed polypeptides have GDP-D-mannose dehydratase activity based on a 51% homology with a GDP-D-mannose dehydratase from another organism. Neither the specification nor the art describe the significance of this activity or a real world use for a protein with this activity" (Ans. 3).

Appellants argue that the polypeptides' utility is independent of "any homology to GDP-D-mannose dehydratases. This utility derives from the selective presence of one or more claimed polypeptides in one strain of *Mycobacterium* compared to another strain, and the ability of a conventional assay to distinguish the two strains by the mere presence (or absence) of the polypeptide" (App. Br. 15).

The Examiner responds that, rather than providing a specific benefit available to the public on the application's filing date, the Specification uses "speculative language to describe the utility of the claimed polypeptides. Throughout the specification, Appellant uses the words, 'could be', 'can be', 'may be' to establish utility for the claimed polypeptides" (Ans. 7).

Moreover, the Examiner argues, the Specification "does not disclose the actual function of the [claimed] purified polypeptides" (*id.* at 8). Thus, the Examiner urges, "without [the] function of the polypeptide, there is no utility" (*id.* at 9).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the

> record, by a preponderance of evidence with due consideration to persuasiveness of argument.
>
> With respect to the rejection presently at issue,
>
> the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.

In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (citation omitted).

We have carefully considered both Appellants' and the Examiner's respective positions. While we understand the Examiner's concerns, in the instant case a preponderance of the evidence supports Appellants' position that an ordinary artisan viewing the Specification would have recognized that the claimed polypeptides were useful for distinguishing between *M. tuberculosis* and *M. bovis*.

The Specification discloses "a method for isolating a polynucleotide of interest that is present in the genome of a mycobacterium strain and/or is expressed by said mycobacterium strain and that is absent or altered in the genome of a different mycobacterium strain" (Spec. 1). Thus, "a polynucleotide of approximately 12.7 kilobases has been isolated that is present in the genome of *M. tuberculosis* but is absent of the genome of *M. bovis* BCG" (*id.* at 9).

The Specification further discloses:

> For diagnostic purposes, this 12.7 kb deletion should allow a rapid PCR screening of tubercle isolates to identify whether they are bovine or human strains. . . . More importantly, assuming that some of the gene products from this region represent proteins with antigenic properties, it could be

> possible to develop a test that can reliably distinguish between the immune response induced by vaccination with *M. bovis* BCG vaccine strains and infection with *M. tuberculosis* or that the products (e.g. polysaccharides) are specific immunogens.

(*Id.* at 11.)

It is undisputed that the polypeptides recited in the claims are encoded by (sub)sequences of the nucleotide sequence described in the Specification as being present in *M. tuberculosis*, but not in *M. bovis*. We therefore agree with Appellants that an ordinary artisan would have recognized that, because a sample containing *M. tuberculosis* also contained the claimed polypeptides, whereas a sample containing *M. bovis* did not, a skilled practitioner would be able to distinguish between samples containing *M. tuberculosis* and *M. bovis* in an immunoassay specific for the claimed polypeptides.

The Examiner points to no specific evidence suggesting that an ordinary artisan would have failed to recognize that the claimed polypeptides would have been useful for distinguishing between *M. tuberculosis* and *M. bovis*. Thus, a preponderance of the evidence supports Appellants' position that an ordinary artisan viewing the Specification would have understood, at the time the application was filed, that the claimed polypeptides were useful as immunogenic markers allowing a practitioner to distinguish between samples containing *M. tuberculosis* and *M. bovis*.

It may be true that the function of the polypeptides was not described in the Specification. Given the relevant disclosures in the Specification, however, we agree with Appellants that a skilled artisan would nonetheless have recognized that the polypeptides were useful in distinguishing *M. tuberculosis* from its closely related *M. bovis* strain.

Accordingly, for the reasons discussed, we reverse the Examiner's rejection of claims 51-54 and 57 as lacking utility under 35 U.S.C. § 101.

The Examiner argues that the claimed polypeptides are not enabled, even if a skilled artisan would have considered them useful (Ans. 13). Specifically, the Examiner urges that the claimed polypeptides are asserted as having only 51.9% homology to GDP-D-mannose dehydratase, and that given the large degree of substitution allowable, and the Specification's failure to identify the portion of the molecules critical to enzymatic activity, it is unpredictable whether the claimed polypeptides would have GDP-D-mannose dehydratase activity (*id.* at 14).

We are not persuaded by this argument. As discussed above, we agree with Appellants that an ordinary artisan would have understood the claimed polypeptides to be useful in distinguishing between *M. tuberculosis* and *M. bovis*. The Examiner points to no specific evidence suggesting that a skilled practitioner, given the present Specification's disclosure, would have had to experiment unduly to devise an appropriate immunoassay for distinguishing between the two bacterial strains.

Given this utility, and the absence of specific evidence suggesting that practicing that use required undue experimentation, we are not persuaded that the claimed polypeptides fail to meet the how-to-use prong of the enablement requirement of 35 U.S.C. § 112, first paragraph. We therefore also reverse the Examiner's enablement rejection of claims 51-54 and 57.

REVERSED

cdc

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